

HOGAN & HARTSON L.L.P.

COLUMBIA SQUARE
555 THIRTEENTH STREET, N.W.
WASHINGTON, DC 20004-1109

Tel.: (202) 637-5600

Fax: (202) 637-5910

BRUSSELS

LONDON

PARIS

(Affiliated Office)

PRAGUE

WARSAW

BALTIMORE, MD

BETHESDA, MD

COLORADO SPRINGS, CO

DENVER, CO

McLEAN, VA

IMPORTANT NOTICE TELECOPY/FACSIMILE COVER LETTER

TO: OMB, Attn: Fumie Yokota

DATE: 9/16/2005

FROM: Ann M. Boeckman
202/637-5770

TIME: 9:30:13 AM

TOTAL NO. OF PAGES, INCLUDING COVER: 8

The attached information is **CONFIDENTIAL** and is intended only for the use of the addressee(s) named above. If the reader of this message is not the intended recipient(s) or the employee or agent responsible for delivering the message to the intended recipient(s), please note that any dissemination, distribution or copying of this communication is strictly prohibited. Anyone who receives this communication in error should notify us immediately by telephone and return the original message to us at the above address via the U.S. Mail.

MESSAGE:

FOR INTERNAL PURPOSES ONLY

202-395-6974

TELECOPY/FAX NUMBER:

ATTORNEY BILLING NUMBER: 5008

TELEPHONE CONFIRMATION

Confirmation Report - Memory Send

Page : 001
Date & Time: Sep-16-05 09:25am
Line 1 : +
Line 2 : +
Machine ID : H & H D.C. Office 7W-501

Job number : 764
Date : Sep-16 09:21am
To : 899#5008#606850034#3956974
Number of pages : 008
Start time : Sep-16 09:21am
End time : Sep-16 09:25am
Pages sent : 008
Status : OK
Job number : 764

*** SEND SUCCESSFUL ***

HOGAN & HARTSON L.L.P.
COLUMBIA SQUARE
555 THIRTEENTH STREET, N.W.
WASHINGTON, DC 20004-1109

Tel.: (202) 637-5600
Fax: (202) 637-5910

BRUSSELS
LONDON
PARIS
(Affiliated Office)
PRAGUE
WARSAW
BALTIMORE, MD
BETHESDA, MD
COLORADO SPRINGS, CO
DENVER, CO
McLEAN, VA

IMPORTANT NOTICE
TELECOPY/FACSIMILE COVER LETTER

TO: OMB, Attn: Fumie Yokota
FROM: Ann M. Boeckman
202/637-5770
TOTAL NO. OF PAGES, INCLUDING COVER: 8

DATE: 9/16/2005
TIME: 9:30:13 AM

The attached information is CONFIDENTIAL and is intended only for the use of the addressee(s) named above. If the reader of this message is not the intended recipient(s) or the employee or agent responsible for delivering the message to the intended recipient(s), please note that any dissemination, distribution or copying of this communication is strictly prohibited. Anyone who receives this communication in error should notify us immediately by telephone and return the original message to us at the above address via the U.S. Mail.

MESSAGE:

FOR INTERNAL PURPOSES ONLY
202-395-6974

TELECOPY/FAX NUMBER:
ATTORNEY BILLING NUMBER: 5008
TELEPHONE CONFIRMATION



Kraft Foods

Sheryl A. Marcouiller
Chief Counsel, Food Law
Law and Compliance Department

September 16, 2005

BY FACSIMILE

Office of Information and Regulatory Affairs
The Office of Management and Budget
725 17th Street, N.W.
Washington, D.C. 20503
Attn: Fumie Yokota, Desk Officer for FDA

**Re: Docket No. 2005N-0120; Agency Information Collection
Activities; Submission for Office of Management and Budget
Review; Comment Request; Experimental Study of
Carbohydrate Content Claims on Food Labels; 70 Fed. Reg.
48423 (Aug. 17, 2005)**

Dear Ms. Yokota:

Kraft Foods Global, Inc. (Kraft) appreciates this opportunity to comment on the Food and Drug Administration's (FDA's) plans to study consumer understanding of carbohydrate content claims. Kraft is a \$30 billion global company, the largest food manufacturer in North America, and the second largest worldwide. For over 100 years, Americans have trusted the well-known brands Kraft sells.

As one of the petitioners who have asked FDA to establish science-based carbohydrate nutrient content claims, Kraft has a substantial interest in ensuring that FDA adopts appropriate rules in a timely manner. In response to FDA's first notice concerning this proposed study, we submitted comments to address ways to make the proposed research more productive and consistent with the agency's statutory authority. We recently learned that, although those comments were properly identified and filed in a timely manner, our submission was erroneously miscoded within FDA and placed in the incorrect docket; consequently, FDA has not yet considered our input. We ask that these comments be considered and addressed at this phase. For convenience, a copy of our prior comments is attached.

In the present notice, FDA provides additional details concerning the proposed study. The agency describes plans to examine use of a sugar disclosure (e.g., "See nutrition information for sugar content") with a "good source of carb" claim, together with a Nutrition Facts box indicating that most of the carbohydrate in the food consists of sugars. According to the notice, the "goal of this test is to better understand how consumers react to a 'good source of carb' claim on a product high in sugar and low in other carbohydrates." Based on the three products proposed for this study—bread, soda, and a frozen entrée—we assume that the product to be tested in this manner will be soda.

The 2005 *Dietary Guidelines for Americans*, among other consensus nutrition guidelines, recommend consumption of a variety of nutrient-dense foods and beverages, while limiting intake of added sugars.¹ Accordingly, as Kraft proposed in our petition to establish science-based carbohydrate claims, foods bearing "good source" and similar claims for carbohydrate content should comply with an appropriate limitation for sugars. We had specifically suggested that foods bearing these claims contain no more than 6 g of sugars, with appropriate exceptions for sugars in fruits and vegetables, which are foods recommended for increased consumption. This proposal is consistent with guidelines concerning sugars intake provided in authoritative sources, including the 2005 *Dietary Guidelines* and the Institute of Medicine "Macronutrient Report."²

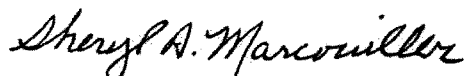
In light of prevailing dietary guidelines, a "good source" or similar claim for carbohydrate appears likely to mislead consumers when used on soda and similar products that are "high in sugar and low in other carbohydrates." Given the likelihood of consumer confusion, FDA has authority to preclude use of such claims without first collecting consumer data. It is not apparent from the August 17, 2005 notice, however, why FDA believes data are needed to assess consumer reaction to a "good source" claim of this type. We recommend that this portion of the planned study be eliminated.

¹ 2005 Dietary Guidelines for Americans ("Consume a variety of nutrient-dense foods and beverages within and among the basic food groups while choosing foods that limit the intake of saturated and *trans* fats, cholesterol, added sugars, salt, and alcohol.").

² IOM, Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Sept. 5, 2002) (prepublication copy).

In addition to this recommendation, we ask that the agency consider our prior comments and modify the design of the proposed study to better reflect the agency's legal authority, regulatory precedent, and sound research practices.

Respectfully submitted,



Sheryl A. Marcouiller

Enclosure

cc: Ms. Peggy Robbins
Office of Management Programs
(HFA-250)
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857



Kraft Foods

Barbara A. Yehling
Senior Consumer Insights Manager
Health and Wellness
Kraft Foods Global, Inc.

Sheryl A. Marcouiller
Chief Counsel, Food Law
Kraft Foods Global, Inc.

June 7, 2005

fdadockets.@oc.fda.gov

BY ELECTRONIC MAIL

Division of Dockets Management
(HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, Maryland 20852

Re: **Docket No. 2005N-0120**; Agency Information Collection Activities; A Proposed Collection; Comment Request; Experimental Study of Carbohydrate Content Claims on Food Labels; 70 Fed. Reg. 18032 (Apr. 8, 2005)

Dear Sir or Madam:

Kraft Foods Global, Inc. (Kraft) appreciates the opportunity to comment on the Food and Drug Administration's (FDA's) plans to conduct a study assessing consumer understanding of carbohydrate content claims. Kraft is a \$30 billion global company, the largest food manufacturer in North America, and the second largest worldwide. For over 100 years, Americans have trusted the well-known brands Kraft sells. Today, Kraft brands are found in more than 99% of all U.S. households.

Kraft is among the petitioners who have asked FDA to establish science-based carbohydrate nutrient content claims; and, accordingly, we have a substantial interest in ensuring that FDA adopts appropriate rules in a timely manner. Historically, FDA rules for nutrient content claims have followed closely the statutory provisions Congress adopted in the Nutrition Labeling and Education Act of 1990 (NLEA). In short, the rules are based on comparing the level of a nutrient in a food to a science-based reference intake or clearly identified reference food. Consequently, while excellent consumer research skills are at the core of our business competencies, to us the role of such research in the context of a proceeding to define science-based nutrient content claims is at best unclear.

In the spirit of making the proposed research more productive, we offer the following suggested modifications to improve the quality of the information generated by the study.

- First, we suggest that the study's focus on both explicit and implied messages be narrowed to better reflect the legal framework under which FDA regulates nutrient content claims. For example, the study evidently would examine whether claims such as "low carbohydrate" may convey some implied meaning to consumers beyond the food's carbohydrate content. This line of inquiry seems inconsistent with FDA's longstanding regulation of nutrient content claims as direct objective statements about the level of a particular nutrient in food relative to an authoritative reference value for that nutrient.
- Second, we recommend making the precise objectives and decision criteria of the study more clear prior to fielding. This process facilitates assessment of the study design, promoting enhancements and appropriate use of data upon completion.
- Third, we recommend that consumers be asked to evaluate all claims within the context of the Nutrition Facts to more closely approximate real-life conditions.

In summary, Kraft asks FDA to revise the study to better reflect the agency's legal authority, regulatory precedent, and sound research practices. The basis for these suggested modifications is described more fully below.

I. Modify the Study Design to Better Reflect the Legal Framework for FDA's Regulation of Nutrient Content Claims

According to the Federal Register notice, the proposed study is intended to enhance FDA's understanding of consumer response to carbohydrate claims on food labels. To accomplish this objective, FDA proposes to examine whether a variety of carbohydrate claims (e.g., "low carb," "x g net carbs," "carbconscious") convey certain implied messages to consumers. For example, the proposed study will examine whether the carbohydrate claims suggest that a food is 1) "healthier" or otherwise more desirable or 2) "lower" or "higher" in total carbohydrate, calories, and other nutrients than the same product without the claim or with a different claim.

To us, these lines of inquiry seem inconsistent with the legal framework for FDA's regulation of nutrient content claims. NLEA created detailed requirements for the regulation of nutrition and health-related claims, including nutrient content claims such as "low carbohydrate." By law, "nutrient content claims" are claims that characterize the

level of a nutrient in food by suggesting that the nutrient is absent or is present in a nutritionally significant amount—in other words, that the food contains “a little” or “a lot” of the nutrient as compared to an authoritative reference value or reference food. Nutrient content claims may be express, and include absolute (e.g., “low fat”) and relative (e.g., “reduced fat”) claims. Nutrient content claims may also be implied (e.g., “healthy”).

Consistent with the NLEA framework, FDA has historically regulated absolute and relative content claims as direct statements about the levels of specific nutrients, and as distinct from each other and from implied claims. This point of view is evident in the separate regulations and unique definitions FDA established for absolute, relative, and implied nutrient content claims. In establishing definitions for absolute and relative nutrient content claims, the agency evaluated each nutrient on its own merits and in light of its science-based reference intake. In defining implied claims such as “healthy,” which obviously convey varied and more complex messages, FDA has appropriately relied on definitions for certain absolute claims, such as “low saturated fat.”

The NLEA framework for nutrient content claims is sound because it accounts for the complexity and variation of everyday diets. Consumers may seek foods with a specific nutrient profile (e.g., “low fat,” “high fiber,” “good source of calcium,” “high protein”) for a myriad of reasons unrelated to other product attributes, including the overall “healthiness” of a food. For instance, an individual with chronically low calcium intakes may be in a good position to consume increased amounts of cheese as a source of calcium, and may do so as part of an overall healthful diet; a person seeking fiber might benefit from consuming a fiber-rich food such as popcorn, even if the popcorn consumed is not “healthy” as defined by FDA. Similarly, a person seeking a cookie as a treat can benefit from choosing a low or reduced fat cookie, even though that cookie is not intended to meet basic nutrition needs in the way that other products might.

It is important as a matter of law and sound nutrition policy that express nutrient content claims and implied claims such as “healthy” be regulated under the distinct criteria and frameworks that FDA has long applied, and not be confused, even in the context of consumer research. An inquiry as to whether express nutrient content claims convey overall product healthfulness or other implied messages is no more appropriate for carbohydrate claims than it was for fat, sodium, or other claims evaluated by FDA. Moreover, to the extent that the effect of a claim on consumer understanding of a product’s healthfulness is of concern, that concern is best addressed through the disclosure criteria applicable for all nutrient content claims.

II. Clearly Identify Study Objectives and Decision Criteria

In our experience, effective consumer research is designed with a clear objective and decision criteria in mind prior to fielding. This ensures that the study design will satisfy its intended purpose/objective by providing the appropriate information necessary to make the decision in question.¹ Given the cost and rigor of the proposed carbohydrate study, it is presumably intended to inform one or more specific decisions; yet, the study description provided in the Federal Register includes no discussion of decision criteria. We urge the agency to establish decision criteria (and publish them) before finalizing the design of this study.

III. The Study Design Should Reflect Real-Life Conditions, Including Access to the Nutrition Facts Panel

The proposed design calls for evaluation of consumer responses to carbohydrate claims presented with and without access to the Nutrition Facts, yet consumers will always have nutrition labeling available when they encounter carbohydrate label claims in the marketplace. We suggest that the agency conform the test to real life conditions and limit evaluation of consumer responses to scenarios where the nutrition information is available.

* * * * *

In summary, Kraft requests that FDA carefully reevaluate the study design and modify it as described above to better reflect the agency's legal authority, regulatory precedent, and sound research practices.

Respectfully submitted,



Barbara Yehling



Sheryl A. Marcouiller

¹ See David Aaker. Marketing Research. New York: John Wiley and Sons, Inc., 1995 ("In general, if research is not going to have an effect on decisions, it is an exercise in futility.") Aaker advocates clarifying upfront what research can accomplish by assessing (1) the various actions under consideration and (2) precise steps that may be taken, given the feasible outcomes of the research.